
CIRM Creates World's First "Translating Center" to Dramatically Accelerate Stem Cell Research

Posted: October 19, 2016

10/19/16

Oakland, CA – California is now home to the most pioneering and progressive approach in moving promising stem cell research out of the lab and into clinical trials in people, thanks to the California Institute for Regenerative Medicine (CIRM).

Today the CIRM Board approved QuintilesIMS as the home of the new CIRM Translating Center. It is the first center in the world designed specifically to overcome the unique challenge of manufacturing, safety testing, and other activities needed to successfully apply to the Food and Drug Administration (FDA) for approval to start a stem cell clinical trial.

C. Randal Mills, Ph.D., CIRM's President and CEO said: "Today it takes about eight years to move a promising stem cell treatment from the lab into human trials. That's eight years many people with serious disease don't have. We aim to cut that time in half. The Translating Center is a major part of how we will accomplish this goal."

The Translating Center will offer stem cell specific testing and support services necessary for a potential new therapy to win FDA approval to start trials in humans. Specifically the center will:

- Offer expert guidance to researchers about the FDA's testing requirements for stem cell products.
- Establish "critical path" testing plans that will minimize the time to initiate a clinical trial.
- Conduct preclinical research activities, including pharmacology and toxicology studies.
- Manufacture stem cell products under the highest quality standards for use in preclinical and clinical studies.

QuintilesIMS, a leading integrated information and technology-enabled healthcare service provider, has deep experience and therapeutic expertise in providing these services.

The center also makes good business sense. CIRM will invest up to \$15 million in funding to help the start-up of the center. In turn, CIRM is projecting a return on that investment within five years through discounts on services to CIRM projects.

The Translating Center will coordinate with the Stem Cell Accelerator – approved by the CIRM Board in June – to help researchers create a comprehensive development plan for their project and coordinate on documentation required for filing regulatory applications. The Accelerator Center award also went to QuintilesIMS.

"We call the combination of the two centers our 'Pitching Machine'," says Dr. Mills, "because they complement each other and work together to overcome the challenges slowing the progress of our most promising stem cell research and accelerate these potential therapies into clinical trials."

The "Pitching Machine" is also helpful to the FDA. The expertise of QuintilesIMS in this area will enable them to create a standardized, uniform approach that best meets the needs of the FDA, making it easier for the agency to evaluate projects in a timely manner.

"With the opening of the Translating and Accelerator Centers, we are doing a lot more than just funding research," says Dr. Mills, "We have created an entire infrastructure, unique to California, that will help us increase the volume, speed and quality of projects moving into clinical trials."

About CIRM

At CIRM, we never forget that we were created by the people of California to accelerate stem cell treatments to patients with unmet medical needs, and act with a sense of urgency to succeed in that mission.

To meet this challenge, our team of highly trained and experienced professionals actively partners with both academia and industry in

a hands-on, entrepreneurial environment to fast track the development of today's most promising stem cell technologies.

With \$3 billion in funding and approximately 300 active stem cell programs in our portfolio, CIRM is the world's largest institution dedicated to helping people by bringing the future of cellular medicine closer to reality.

For more information, go to www.cirm.ca.gov.

Source URL: <http://www.cirm.ca.gov/about-cirm/newsroom/press-releases/10192016/cirm-creates-world%20%99s-first-%E2%80%99translating-center%E2%80%9D>